The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

Paper No. 26

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte JOSEPH R. BYRUM,
THOMAS J. La ROSA, and
GREGORY R. HECK,

Appeal No. 2002-0078
Application No. 09/206,040

ON BRIEF

Before STONER, Chief Administrative Patent Judge, and WILLIAM F. SMITH and SCHEINER, Administrative Patent Judges.

WILLIAM F. SMITH, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from an examiner's final rejection of claims 1 through 3, which read as follows:[1]

[1] A copy of SEQ ID No. 1 is attached to this opinion.

1. A nucleic acid molecule isolated from other nucleic acid molecules and comprising SEQ ID No. 1 or its complement.

2. A nucleic acid molecule consisting of SEQ ID No. 1 or its complement.

3. A nucleic acid molecule isolated from other nucleic acid molecules and consisting essentially of SEQ ID No. 1 or its complement.

Claims 1 through 3 stand rejected under 35 U.S.C. § 101 (utility) and § 112, first paragraph (enablement). Claims 1 and 3 also stand rejected under 35 U.S.C. § 112, first paragraph (written description). We affirm the utility and enablement rejections and do not reach the merits of the written description rejection. Since our reasons for concluding that the claims lack patentable utility differ substantially from those advanced by the examiner, we denominate our affirmance as a new ground of rejection under 37 CFR § 1.196(b).

Background

The nucleic acid molecule set forth in SEQ ID No. 1 is stated to be an expressed sequence tag (EST) obtained from soybean plant material. Specification, page 14 ("The present invention provides soybean ESTs . . .."), Appeal Brief, page 2 ("The invention is directed to nucleic acid molecules reciting the sequence of an expressed sequence tag . . .."). ESTs are "short sequences of randomly selected clones from a cDNA (or complementary DNA) library which are representative of the cDNA inserts of these randomly selected clones." Specification, page 1. As explained in Examples 1 and 2 of the specification, the claimed EST was obtained from a cDNA library prepared

from young soybean seeds collected from young pods.[2] The cDNA library from which the nucleic acid molecule set forth in SEQ ID No. 1 was isolated has been designated LIB3049. Specification, page 18.

The three claims before us for review define the claimed nucleic acid molecule as comprising, consisting of, or consisting essentially of SEQ ID No. 1 or its complement. Appellants explain that a nucleic acid molecule is said to be the 'complement' of another nucleic acid molecule if it exhibits complete complementarity, stating "[a]s used herein, molecules are said to exhibit 'complete complementarity' when every nucleotide of one of the molecules is complementary to a nucleotide of the other." Specification, page 16. However, appellants back away from this absolute definition of "complement" stating that "[d]epartures from complete complementarity are permissible, as long as such departures do not completely preclude the capacity of the molecules to form a double stranded structure." Specification, page 17.

The specification sets forth a number of utilities for the nucleic acid molecule of SEQ ID No. 1 which are summarized by the examiner as follows:

> The utilities disclosed for the EST of SEQ ID NO: 1 or fragment thereof, or a nucleic acid molecule comprising same are:

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[2] The record contains conflicting statements in regard to the source of the cDNA library from which the claimed EST was isolated. Example 1 states that the cDNA library was obtained from young seeds collected from young pods while page 24 of the specification states that the nucleic acid molecules of the present invention "were isolated from pods and seeds." (Emphasis added). Appellants summarize their invention at page 2 of the Appeal Brief stating that "[t]he claimed nucleic acid molecules were derived from a cDNA collection prepared from young soybean pods." Thus, it is unclear whether the cDNA library was obtained from young seeds, young pods, or a combination of young seeds and young pods. If prosecution is resumed on this subject matter, appellants should clarify the source of the claimed nucleic acid molecule.

sequences corresponding to the claimed nucleic acid molecule in a genome, and then use as a probe for detecting the polymorphisms, which serve as a molecular marker, either a) for a mutation affecting the expression of a product encoded, at least in part, by the claimed nucleic acid molecule (specification, pages 27-28) or b) for a desirable trait that is genetically linked to the polymorphism (specification, pages 35-36);

-Use of the EST as a probe for detecting a physical map location, e.g. as a marker in in situ hybridization;

-Use as a probe or source of PCR primers either to isolate other nucleic acid molecules (e.g. complete cDNA, protein coding sequence, genomic fragment, promoter, start of a chromosome walk) from the same organism or different organisms, i.e. other plants, or to detect other nucleic acid molecules (e.g. mRNA, chromosomal region, chromosome). Disclosed for the latter, for example, is to detect the mRNA in different tissues or as a measure of protein expression from the mRNA (based on mRNA levels), particularly if there is a mutation (hypothetical) affecting expression;

-Use of the EST as an antisense inhibitor of the corresponding mRNA; and

-Use as a probe to identify or isolate proteins that might bind to the EST sequence.

Examiner's Answer, pages 4-5. In the opinion of the examiner:

> Each of these utilities requires additional knowledge about the EST before the EST can be used for a specific purpose, such as: whether there are sequence polymorphisms linked to the gene corresponding to the EST and, if so, their identify; the map location of the corresponding gene; the sequence of the corresponding complete mRNA sequence, protein coding sequence or genomic sequence; the function of the protein encoded by the corresponding mRNA; the identity and phenotype, if any, of a mutation in the corresponding gene; the tissue distribution of the corresponding mRNA and tissue-specific expression levels; etc. The specification does not provide any such information specific to the disclosed EST. Consequently, the disclosed utilities are non-specific utilities, since any of the general disclosed utilities would apply equally to any uncharacterized nucleic acid molecule from soybean in particular, or plants in general.

Examiner's Answer, paragraph bridging pages 5-6.

The examiner concludes:

> In Brenner v. Manson, 148 USPQ 689, 696 (US, 1966), the Court held that "Congress intended that no patent be granted on a chemical compound whose sole "utility" consists of its potential role as an object of use-testing", and stated, in context of the utility requirement, that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion." The original disclosure lacks any successful conclusion for even one of the vague and general utilities disclosed. Thus, no "substantial" or "real world" utility has been disclosed.

Examiner's Answer, page 6.

Appellants urge that the claims on appeal possess patentable utility under 35 U.S.C. § 101. See, e.g., Appeal Brief, page 19 ("Applicants have disclosed numerous utilities for the claimed nucleic acid molecules, and have submitted evidence proving that the claimed nucleic acid molecules work for at least two of the disclosed utilities."). In presenting their case on appeal, appellants focus on use of the claimed nucleic acid molecules to identify the presence or absence of a polymorphism, and their use as probes or as a source for primers. Appeal Brief, pages 11-18.

In support of their position, appellants rely upon the declaration of Dr. Roger C. Wiegand.[3] Dr. Wiegand states that "EST databases are useful tools that may be used to select clones for further research, or to compare sequences in the database with other sequences, but the nucleic acid molecules represented by the ESTs themselves have value beyond that associated with their ESTs." Wiegand decl., para. 6. Dr. Wiegand also states that "ESTs are typically used to develop molecular markers,

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[3] Appellants also refer to a La Rosa declaration in the heading appearing on page 4 of the Appeal Brief. However, the La Rosa declaration is only directed to the deposit of clone designated LIB-3049-003-Q1-E1-H7 with the ATCC.

hybridization probes, amplification primers, and to identify the presence or absence of polymorphisms." Wiegand decl., para. 7. Dr. Wiegand also discusses the results of tests performed with a nucleic acid molecule "having the sequence of SEQ ID No. 1" in regard to its use as a hybridization probe in detection of genetic polymorphism, stating:

> 19. The results of the northern blots indicate that a nucleic acid molecule having the sequence of SEQ ID NO: 1 can be synthesized and successfully used as a hybridization probe, and that such a molecule will hybridize to a naturally occurring soybean nucleic acid molecule. Accordingly, a nucleic acid molecule having SEQ ID NO: 1 is useful as a hybridization probe for expression profiling or other purposes.
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> 21. I believe that a nucleic acid molecule comprising the EST of SEQ ID NO: 1 possesses the practical utility of being useful for detecting polymorphisms because scientists under my supervision performed Southern blots to test if a synthetic nucleic acid molecule based on SEQ ID NO: 1 would detect polymorphisms. It did.
>
> 23. The results of the Southern blots indicate that a nucleic acid molecule having the sequence of SEQ ID NO: 1 can be synthesized and successfully used to detect polymorphisms in soybean chromosomal DNA. Accordingly, a nucleic acid molecule having the sequence of SEQ ID NO: 1 is useful for detecting polymorphisms in order to develop a genetic map, determining if a plant carries the gene for a particular trait, determining the copy number of a particular gene in a plant, or for other purposes.

Wiegand decl., paras. 19, 21, and 23.

In regard to claim construction, the examiner states in the context of setting forth the enablement rejection:

> The recitation of "consisting essentially of" in claim 3 has been treated as being equivalent to "comprising", as recited in claim 1. There is nothing on the record to indicate how "consisting essentially of" alters the scope of claim 3 compared to claim 1. Thus, claim 3 would not exclude any embodiment embraced by claim 1.

Examiner's Answer, page 7. The examiner has determined that claims 1 and 3 embrace an "essentially infinite genus of nucleic acid molecules" (Examiner's Answer, page 8) and that the specification does not "teach the maximum length or locations (5' end, 3' end, or both ends, of nucleic acid sequence(s) that could be added to SEQ ID NO: 1, that would not interfere with its disclosed use as a hybridization probe." Id.. The examiner is also of the opinion that "[s]ince the claims embrace adding any and all nucleic acid sequences to the core nucleic acid molecule SEQ ID NO: 1, one cannot predict whether or not the additional nucleic acid sequence[s] added would hybridize to a target nucleic acid molecule other than the intended target nucleic acid molecule. When such a situation occurs, and more than one nucleic acid molecule is amplified or detected in hybridization, the skilled artisan would have no information that would allow the desired target nucleic acid molecule to be distinguished from a nucleic acid molecule that was targeted by the added nucleic acid sequences." Examiner's Answer, page 9. The examiner concludes:

> Consequently, making the myriad of nucleic acid molecules embraced by the claims and testing the suitability of each for use as a probe or primer for the disclosed utilities in the absence of guidance or examples would require excessive trial and error experimentation due to the unpredictability involved, and would therefore require undue experimentation.

Id..

In reaching the conclusion of undue experimentation, the examiner did not perform an analysis of the so-called Wands factors. In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404, (Fed. Cir. 1988). In contrast to the examiner's position,

appellants provide an analysis of the Wands factors in support of their position that the claim are enabled. Appeal Brief, pages 27-36.

The examiner's reasoning in regard to the written description rejection is:

> Claims 1 and 3 are drawn to nucleic acid molecules "comprising" or "consisting essentially of" the EST of SEQ ID NO: 1; and therefore to an astronomically large genus of nucleic acid molecules comprising SEQ ID NO: 1 even solely considering nucleic acid sequences and ignoring nucleic acid molecules comprising non-nucleotide moieties such as detectable labels. The specification does not explicitly disclose any nucleic acid molecules that "comprise" or "consist essentially of" SEQ ID NO: 1, other than that of SEQ ID NO: 1 itself (either unlabeled or labeled with a detectable non-nucleotide moiety such as a fluorophor) and the clone from which the sequence was derived. Any additional cDNA sequence that may be present on the clone was not described other than by deposit. No nucleic acid molecules are disclosed wherein the nucleic acid sequence is extended beyond SEQ ID NO: 1, other than solely by implication a larger EST or mRNA comprising SEQ ID NO: 1. However, the specification does not disclose the structure of any such larger nucleic acid molecule or EST or mRNA. The disclosure of the single nucleic acid molecule set forth as SEQ ID NO: 1 does not adequately describe the astronomically large number of possible nucleic acid molecules embraced by claims 1 and 3.

Examiner's Answer, page 10.

Appellants respond that the specification reflects their "possession" of the claimed invention. Appeal Brief, pages 36-41.

Discussion

As always, we begin our analysis by construing the claims as "the name of the game is the claim." In re Hiniker Co., 150 F.3d 1362, 1369, 47 USPQ2d 1523, 1529 (Fed. Cir. 1998)(citing Giles Sutherland Rich, Extent of Protection and Interpretation of Claims--American Perspectives, 21 Int'l Rev. Indus. Prop. & Copyright L. 497, 499 (1990). See also, Panduit Corp. v. Dennison Manufacturing Co., 810 F.2d 1561, 1567-

68, 1 USPQ2d 1593, 1597 (Fed. Cir.), cert. denied, 481 U.S. 1052 (1987) ("Analysis begins with a key legal question--what is the invention claimed? ... Claim interpretation ... will normally control the remainder of the decisional process."). The claim analysis which appears in the Appeal Brief and the Examiner's Answer provides little assistance in our review of the issues presented in this appeal. For example, appellants state "[t]he genus of claimed nucleic acid molecules, i.e., nucleic acid molecules 'comprising,' 'consisting of,' and 'consisting essentially of' SEQ ID No. 1 have been described by the recitation of a 'basic and novel' common structural feature - the nucleotide sequence of SEQ ID No. 1 - which distinguishes them from nucleic acid molecules not in the claimed genus." Appeal Brief, page 4. Appellants have not explained on this record how a nucleic acid molecule which "comprises" the nucleotide sequence of SEQ ID No. 1 differs from a nucleic acid molecule "consisting of" or "consisting essentially of" the nucleotide sequence of SEQ ID No. 1. Appellants' arguments for the most part are couched in vague, non-specific terms such as "the claimed nucleic acid molecules," instead of referring to actual claims and the language used therein. See, e.g., Appeal Brief, page 8, first full paragraph ("Applicants have asserted specific utilities for the claimed nucleic acid molecules...."). Importantly, appellants have not offered any assistance in the Appeal Brief as to how broadly or narrowly they would have the word "complement" construed as it is used in claims 1-3 on appeal.

The one specific statement we find in the Examiner's Answer construing the claims on appeal is contrary to governing precedent and, thus, is in error. The examiner states "[t]he recitation of 'consisting essentially of' in claim 3 has been treated

as being equivalent to 'comprising', as recited in claim 1. There is nothing on the record to indicate how 'consisting essentially of' alters the scope of claim 3 compared to claim 1. Thus, claim 3 would not exclude any embodiment embraced by claim 1." Examiner's Answer, page 7, fourth full paragraph. The examiner's holding that the transitional phrase "consisting essentially of" is equivalent to the transitional phrase "comprising" is contrary to long established precedent. In re Janakirama-Rao, 317 F.2d 951, 954, 137 USPQ 893, 896 (CCPA 1963) ("The word 'essentially' opens the claims to the inclusion of ingredients which would not materially affect the basic and novel characteristics of appellants' compositions as defined in the balance of the claim, according to the applicable law."). Assuming the examiner is correct in concluding there is "nothing on the record" that would allow the examiner to distinguish between a claim using the transitional phrase "consisting essentially of" and the same claim using the transitional phrase "comprising," we do not find that to be sufficient justification for the examiner to upend decades of precedent. These transitional phrases have defined meanings in the law. The fact that an examiner is having trouble distinguishing the scope of claims 1 and 3 on the basis of the transitional phrases used may, however, be an indication that the claims are indefinite under 35 U.S.C. § 112, second paragraph. In re Hammack, 427 F.2d 1378, 1382, 166 USPQ 204, 208 (CCPA 1970) (Purpose of 35 U.S.C. § 112, second paragraph, "is to provide those who would endeavor, in future enterprise, to approach the area circumscribed by the claims of a patent, with the adequate notice demanded by due process of law, so that they may more readily and

accurately determine the boundaries of protection involved and evaluate the possibility of infringement and dominance.").

Additional ambiguity is injected in the claims by use of the word "complement" and the reference in the claims to SEQ ID No. 1. As discussed above, the specification contains a very strict definition of complement, i.e., every nucleotide of one of the molecules is complementary to a nucleotide of another nucleic acid molecule, while at the same time indicating that the nucleic acid molecules according to the present invention may depart from "complete complementarity." Thus, determining what constitutes a "complement" of the claimed nucleic acid molecules as that word is used in the claims on appeal is problematic.

The reference in the claims to SEQ ID No. 1 is also subject to interpretation as appellants state "[a]n aspect to the present invention is that the nucleic acid molecules of the present invention include nucleic acid molecules that are degenerate of that set forth in SEQ ID No. 1." Specification, page 18. As acknowledged by appellants, "a nucleic acid molecule is degenerate of another nucleic acid molecule when the nucleic acid molecules encode for the same amino acid sequences but comprise different nucleotide sequences." Id.. The nucleotide sequence depicted in SEQ ID No. 1 does not indicate the reading frame or contain an assigned amino acid sequence. Without such knowledge, it is unclear how one would consider a given nucleotide sequence to be "degenerate" of that depicted in SEQ ID No. 1. Thus, if the claims on appeal are to be read as encompassing degenerate nucleotide sequences, the determination of the identity of such degenerate molecules would be difficult.

Having a firm understanding of the scope of the claims under review is also necessary in evaluating appellants' rebuttal evidence in regard to the utility rejection. For example, Dr. Wiegand states "the synthetic probe is a true enough copy of SEQ ID No. 1 for use as a probe to demonstrate the utility of nucleic acid molecules characterized by SEQ ID No. 1." Wiegand Declaration, para. 16. (Emphasis added). If one cannot readily determine whether a given nucleotide sequence is within or without the scope of the claims under review, it is difficult to assign weight to evidence which is based upon "a true enough copy of SEQ ID No. 1."

The ability or inability to reasonably ascertain the metes and bounds of a claim is important in determining whether the claim possesses patentable utility under § 101 as all embodiments within a claim must meet the utility requirement. In re Langer, 503 F.2d 1380, 1394, 183 USPQ 288, 299 (CCPA 1974) ("We hold that appellant's evidence of record is insufficient to rebut the prima facie case for lack of utility in the subject matter (other than [preferred species]) recited in these claims."). In similar fashion, it is difficult to determine whether a given claim is enabled throughout its scope without undue experimentation without first knowing the scope of the claim under review. In re Moore, 439 F.2d 1232, 1236, 169 USPQ 236, 238 (CCPA 1971) ("Once having determined that the subject matter defined by the claims is particular and definite, the analysis then turns to the first paragraph of § 112 to determine whether the scope of protection sought is supported and justified by the specification disclosure.") (Emphasis added). The same holds true in considering the written description requirement of the first paragraph of § 112. Enzo Biochem, Inc. v. Gen-Probe, Inc., 296

F.3d 1316, 1327, 63 USPQ2d 1609, 1615 (Fed. Cir. 2002) ("On remand, the court should determine whether a person of skill in the art would glean from the written description, including information obtainable from the deposits of the claimed sequences, subsequences, mutated variants and mixtures sufficient to demonstrate possession of generic scope of the claims.").

Reaching a decision on a record such as this is difficult. However, we do know that the claims on appeal include one discrete and definite embodiment not subject to interpretation, alternative construction, ambiguity or spin of any type, i.e., the precise 469 nucleotide sequence set forth in SEQ ID No. 1 without any preceding or trailing nucleotides.

Thus, we will proceed to a decision on the issues raised in this appeal to the extent that claims 1 through 3 on appeal include the nucleic acid molecule defined by the 469 nucleotide sequence set forth in SEQ ID No. 1 without alteration or any preceding or trailing nucleotides as this is the only subject matter that we can say with certainty is included within each of the claims.

1. Utility.[4]

The starting point for determining whether a nucleic acid molecule having the 469 nucleotide sequence set forth in SEQ ID No. 1 possesses utility under 35 U.S.C.

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[4] Appellants refer to the "Revised Utility Examination Guidelines, 64 Fed. Reg. 71440, 71442" in presenting their case on appeal. See, e.g., Appeal Brief, page 5. Those guidelines were superseded by Utility Examination Guidelines, 66 Fed. Reg. 1092 (Jan. 5, 2001). Although the Appeal Brief and the Examiner's Answer were prepared after that date, it does not appear that either appellants or the examiner considered the latest version of the guidelines in preparing the briefing in this appeal. Be that as it may, we note that the utility guidelines expressly state that they do not have the force or effect of law, see id. at 1098, and our analysis is based instead on controlling precedent. We note, however, that our conclusion is consistent with the utility guidelines.

§ 101 is Brenner v. Manson, 383 U.S. 519, 148 USPQ 689 (1966). The Court stated "the basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. Unless and until [an invention] is refined and developed to this point--where specific benefit exists in currently available form--there is insufficient justification for permitting an applicant to engross what may prove to be a broad field." Id. at 534-35, 148 USPQ at 695.[5] In considering the issues presented in this appeal, special attention must be paid to the Court's statement that a patent should issue only when an invention possesses "substantial utility," i.e., "where a specific benefit exists in currently available form." Whether a claimed invention is useful under 35 U.S.C. § 101 is a question of fact. Cross v. Iizuka, 753 F.2d 1040, 1044 n.7, 224 USPQ 739, 742 n.7 (Fed. Cir. 1985).

At issue in Brenner was a claim to "a chemical process which yields an already known product whose utility—other than as a possible object of scientific inquiry—ha[d] not yet been evidenced." Id. at 529, 148 USPQ at 693. The Patent Office had rejected the claimed process for lack of utility, on the basis that the product produced by the claimed process had not been shown to be useful. See id. at 521-22, 148 USPQ at 690. On appeal, the Court of Customs and Patent Appeals reversed, on the basis that

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[5] In discussing the issue of utility under 35 U.S.C. § 101, the Federal Circuit and the Court of Customs and Patent Appeals since Brenner, has used the phrases "substantial utility" and "practical utility" interchangeably. See, e.g., Fujikawa v. Wattanasin, 93 F.3d 1559, 1963-1964, 39 USPQ2d 1895, 1898-1899 (Fed. Cir. 1996) ("It is well established that a patent may not be granted to an invention unless substantial or practical utility for the invention has been discovered and disclosed.").

"where a claimed process produces a known product it is not necessary to show utility for the product." Id. at 522, 148 USPQ at 691.

The Brenner Court noted that although § 101 requires that an invention be "useful," that "simple, everyday word can be pregnant with ambiguity when applied to the facts of life." Id. at 529, 148 USPQ at 693. Thus,

> [i]t is not remarkable that differences arise as to how the test of usefulness is to be applied to chemical processes. Even if we knew precisely what Congress meant in 1790 when it devised the "new and useful" phraseology and in subsequent re-enactments of the test, we should have difficulty in applying it in the context of contemporary chemistry, where research is as comprehensive as man's grasp and where little or nothing is wholly beyond the pale of "utility"—if that word is given its broadest reach.

Id. at 530, 148 USPQ at 694.[6]

The Court, finding "no specific assistance in the legislative materials underlying § 101," based its analysis on "the general intent of Congress, the purposes of the patent system, and the implications of a decision one way or the other." Id. at 532, 148 USPQ at 695. The Court concluded that "[t]he basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. Unless and until a process is refined and developed to this point—where specific benefit exists in currently available form—there is insufficient justification for permitting an applicant to engross what may prove to be a broad field." Id. at 534-35, 148 USPQ at 695.

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[6] The invention at issue in Brenner was a process, but the Court expressly noted that its holding "would apply equally to the patenting of the product produced by the process." Id. at 535, 148 USPQ at 695-96.

The Court considered and rejected the applicant's argument that attenuating the requirement of utility "would encourage inventors of new processes to publicize the event for the benefit of the entire scientific community, thus widening the search for uses and increasing the fund of scientific knowledge." The Court noted that, while there is value to encouraging disclosure, "a more compelling consideration is that a process patent in the chemical field, which has not been developed and pointed to the degree of specific utility, creates a monopoly of knowledge which should be granted only if clearly commanded by the statute. Until the process claim has been reduced to production of a product shown to be useful, the metes and bounds of that monopoly are not capable of precise delineation. It may engross a vast, unknown, and perhaps unknowable area. Such a patent may confer power to block off whole areas of scientific development." Id. at 534, 148 USPQ at 695.

The Court took pains to note that it did not "mean to disparage the importance of contributions to the fund of scientific information short of the invention of something 'useful,'" and that it was not "blind to the prospect that what now seems without 'use' may tomorrow command the grateful attention of the public." Id. at 535-36, 148 USPQ at 696. Those considerations did not sway the Court, however, because "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion." Id.

Subsequent decisions of the CCPA and the Court of Appeals for the Federal Circuit have added further layers of judicial gloss to the meaning of § 101's utility requirement. The first opinion of the CCPA applying Brenner was In re Kirk, 376 F.2d

936, 153 USPQ 48 (CCPA 1967). The invention claimed in Kirk was a set of steroid derivatives said to have valuable biological properties and to be of value "in the furtherance of steroidal research and in the application of steroidal materials to veterinary or medical practice." Id. at 938, 153 USPQ at 50. The claims had been rejected for lack of utility. In response, the applicants submitted an affidavit which purportedly "show[ed] that one skilled in the art would be able to determine the biological uses of the claimed compounds by routine tests." Id. at 939, 153 USPQ at 51.

The court held that "nebulous expressions [like] 'biological activity' or 'biological properties'" did not adequately convey how to use the claimed compounds. Id. at 941, 153 USPQ at 52. Nor did the applicants' affidavit help their case: "the sum and substance of the affidavit appear[ed] to be that one of ordinary skill in the art would know 'how to use' the compounds to find out in the first instance whether the compounds are—or are not—in fact useful or possess useful properties, and to ascertain what those properties are." Id. at 942, 153 USPQ at 53.

The Kirk court held that an earlier CCPA decision, holding that a chemical compound meets the requirements of § 101 if it is useful to chemists doing research on steroids, had effectively been overruled by Brenner. "There can be no doubt that the insubstantial, superficial nature of vague, general disclosures or arguments of 'useful in research' or 'useful as building blocks of value to the researcher' was recognized, and clearly rejected, by the Supreme Court" in Brenner. See Kirk, 376 F.2d at 945, 153 USPQ at 55.

More recently, in In re Ziegler, 992 F.2d 1197, 26 USPQ2d 1600 (Fed. Cir. 1993), the Federal Circuit considered the degree of specificity required to show utility for a claim to polypropylene. The U.S. application on appeal in Ziegler claimed priority to a German application filed in 1954. "In the German application, Ziegler disclosed only that solid granules of polypropylene could be pressed into a flexible film with a characteristic infrared spectrum and that the polypropylene was 'plastic-like.'" Id. at 1203, 26 USPQ2d at 1605. "Ziegler did not assert any practical use for the polypropylene or its film, and Ziegler did not disclose any characteristics of the polypropylene or its film that demonstrated its utility." Id. The court held that the German application did not satisfy the requirements of § 101 and therefore could not be relied on to overcome a rejection based on an intervening reference. See id., 26 USPQ2d at 1606. "[At] best, Ziegler was on the way to discovering a practical utility for polypropylene at the time of the filing of the German application; but in that application Ziegler had not yet gotten there." Id., 26 USPQ2d at 1605.

On the other hand, the CCPA reversed a rejection for lack of utility in In re Jolles, 628 F.2d 1322, 206 USPQ 885 (CCPA 1980). The applicant in Jolles claimed pharmaceutical compositions that were disclosed to be useful in treating acute myeloblastic leukemia. See id. at 1323, 206 USPQ at 886. The active ingredients in the compositions were closely related to daunorubicin and doxorubicin, both of which were "well recognized in the art as valuable for use in cancer chemotherapy." Id., 206 USPQ at 887. The applicant also submitted declaratory evidence showing that eight of the claimed compositions were effective in treating tumors in a mouse model, and one

was effective in treating humans. See id. at 1323-24, 206 USPQ at 887-88. The court noted that the data derived from the mouse model were "relevant to the treatment of humans and [were] not to be disregarded," id. at 1327, 206 USPQ at 890, and held that the evidence was sufficient to support the asserted therapeutic utility. See id. at 1327-28, 206 USPQ at 891.

The Federal Circuit held in Cross v. Iizuka, 753 F.2d 1040, 224 USPQ 739 (Fed. Cir. 1985), that in vivo testing (as in Jolles) was not necessarily required to show utility in the pharmaceutical context. The Cross court stated that "[it] is axiomatic that an invention cannot be considered 'useful,' in the sense that a patent can be granted on it, unless substantial or practical utility for the invention has been discovered and disclosed where such utility would not be obvious." Id. at 1044, 224 USPQ at 742 (citing Brenner v. Manson). The court "perceive[d] no insurmountable difficulty, under appropriate circumstances, in finding that the first link in the screening chain, in vitro testing, may establish a practical utility for the compound in question." Id. at 1051, 224 USPQ at 748. Successful in vitro testing could provide an immediate benefit to the public, by "marshal[ling] resources and direct[ing] the expenditure of effort to further in vivo testing of the most potent compounds . . ., analogous to the benefit provided by the showing of an in vivo utility." Id. On the facts of that case – successful in vitro testing supplemented by similar in vitro and in vivo activities of structurally similar compounds – the court held that in vitro activity was sufficient to meet the requirements of § 101. See id.

The Federal Circuit confirmed in In re Brana, 51 F.3d 1560, 34 USPQ2d 1436 (Fed. Cir. 1995), that human testing is not necessary to establish utility for a method of treatment. The invention claimed in Brana was a group of compounds disclosed to have antitumor activity. See id. at 1562, 34 USPQ2d at 1437-38. The specification disclosed that the claimed compounds had higher antitumor activity than related compounds known to have antitumor activity, and the applicants provided declaratory evidence of in vivo activity against tumors in a mouse model. See id., 34 USPQ2d at 1438. The court held that these data were sufficient to satisfy § 101; usefulness in patent law does not require that the invention be ready to be administered to humans. See id. at 1567, 34 USPQ2d at 1442.

Several lessons can be drawn from Brenner and its progeny. First, § 101's requirement that an invention be "useful" is not to be given its broadest reach, such that little or nothing of a chemical nature would be found to lack utility. See Brenner, 383 U.S. at 530, 148 USPQ at 694. Thus, not every "use" that can be asserted will be sufficient to satisfy § 101. For example, the steroid compound at issue in Brenner was useful as a possible object of scientific inquiry, and the polypropylene claimed in Ziegler was useful for pressing into a flexible film, yet both lacked sufficient utility to satisfy § 101. See Brenner, 383 U.S. at 529, 148 USPQ at 696; Ziegler, 992 F.2d at 1203, 26 USPQ2d at 1605.

Rather than setting a de minimis standard, § 101 requires a utility that is "substantial", i.e., one that provides a specific benefit in currently available form. Brenner, 383 U.S. at 534-35, 148 USPQ at 695. This standard has been found to be

met by pharmaceutical compositions shown to be useful in mouse models and in humans for treating acute myeloblastic leukemia (Jolles, 628 F.2d at 1327-28, 206 USPQ at 891); by evidence showing successful in vitro testing supplemented by similar in vitro and in vivo activities of structurally similar compounds (Cross, 753 F.2d at 1051, 224 USPQ at 748); and by evidence showing in vivo antitumor activity in mice, combined with a disclosure that the claimed compounds had higher antitumor activity than a related compound known to have antitumor activity (Brana, 51 F.3d at 1567, 34 USPQ2d at 1442).

By contrast, Brenner's standard has been interpreted to mean that "vague, general disclosures or arguments of 'useful in research' or 'useful as building blocks of value to the researcher'" would not satisfy § 101. See Kirk, 376 F.2d at 945, 153 USPQ at 55 (interpreting Brenner). Likewise, a disclosure of a "plastic-like" polypropylene capable of being pressed into a flexible film was held to show that the applicant was "at best . . . on the way to discovering a practical utility for polypropylene at the time of the filing," but not yet there. Ziegler, 992 F.2d at 1203, 26 USPQ2d at 1605.

With these principles in mind we turn to the issues at hand. Of the many utilities asserted in the specification, two have received the most attention in the briefing in this appeal, i.e., identification and detection of polymorphisms and use as probes or as a source for primers. We shall focus on these asserted utilities first and then address the other arguments set forth in the briefing.

a. Polymorphisms

This utility is discussed at pages 28-35 of the specification in terms of what polymorphisms are and how one would go about determining the existence of a polymorphism. The discussion in this portion of the specification is not specific to the 469 nucleotide molecule depicted in SEQ ID No. 1. Nor does the specification explain why the 469 nucleotide molecule of SEQ ID No. 1 would in fact be useful in detecting polymorphisms. Rather, appellants' argument is that "the claimed nucleic acid molecules have utility even if the absence of a particular polymorphism is detected. Indeed, the absence of a polymorphism usually demonstrates that the two (or more) populations being compared share a common genetic heritage." Appeal Brief, page 14. In other words, appellants' position is that an EST by definition possesses patentable utility because it can be used by itself in determining whether populations share a common genetic heritage. While that may be a "utility," we do not find that it is a substantial utility.

Without knowing any further information in regard to the gene represented by an EST, as here, detection of the presence or absence of a polymorphism provides the barest information in regard to genetic heritage and can be viewed to be at the lower end of the utility spectrum. At the high end of the utility spectrum would be information gleaned from detecting the presence or absence of a polymorphism when it is known what effect the gene from which the EST is derived has in the development and/or phenotype of the plant. Somewhere between having no knowledge of the gene and its role in the plant's development and phenotype (the present circumstances) and having

complete knowledge of the gene and its role in the plant's development and/or phenotype lies the line between "utility" and "substantial utility." We need not draw the line or further define it in this case because the facts in this case represent the lowest end of the spectrum, i.e., an insubstantial use.

Dr. Wiegand's declaration does not aid appellants in this aspect of their case. Polymorphism as a utility is discussed primarily in paragraphs 20-23 of the declaration. Two probes were used in Dr. Wiegand's work, "a synthesized nucleic acid molecule based on overlapping oligomers matching SEQ ID No. 1; and a probe derived from the plasmid that carries clone LIB3049-003-Q1-E1-H7, from which SEQ ID No. 1 was determined." Dr. Wiegand concludes that "a nucleic acid molecule having a sequence of SEQ ID No. 1 can be synthesized and successfully used to detect polymorphisms in soybean chromosomal DNA. Accordingly, a nucleic acid molecule having the sequence of SEQ ID NO. 1 is useful for detecting polymorphisms in order to develop a genetic map, determining if a plant carries the gene for a particular trait, determining the copy number of a particular gene in a plant, or for other purposes."

First, the precise identity of the nucleic acid molecules used in Dr. Wiegand's work is unclear. As stated above, we are limiting our consideration of the issues raised in this appeal as they pertain to the precise 469 nucleotide molecule set forth in SEQ ID No. 1. Dr. Wiegand's conclusions are premised upon use of "a nucleic acid molecule having the sequence of SEQ ID No. 1." It is unclear whether the probes used contained only the specific 469 nucleotides depicted in SEQ ID No. 1 or contained

additional nucleotides before and/or after the specific 469 nucleotide molecule set forth in SEQ ID No. 1.

In any case, it is not clear how the results reported in the declaration establish a substantial utility. Dr. Wiegand does not state in his declaration that these results provide any significant knowledge. To the contrary, they appear to represent what one might reasonably assume--a given EST may or may not detect a polymorphism in a related organism. While such knowledge may indicate the molecule is "useful" to some degree, we do not find that it represents a substantial utility.[7]

b. Probes or source of primers

Appellants argue that the specification "discloses that the claimed nucleic acid molecules can be used to isolate nucleic acid molecules of other plants and organisms...." Appeal Brief, page 16. While that may be true, it begs the question of what substantial use such knowledge would have? Again, the present specification does not attribute any property in terms of plant trait, or phenotype to the 469

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[7] We are aware that the examiner and appellants have engaged in a discussion on this record as to whether the specific soybean plants used in Dr. Wiegand's work are species and thus, whether the work is relevant in determining the utility issue. However, the manner in which the examiner and appellants have raised this issue in the context of this appeal proceeding does not provide a reasonable basis for its review. As stated by appellants, the issue was raised in an Advisory Action. Appeal Brief, page 15. Appellants responded to the assertions made in the Advisory Action by relying upon a dictionary definition in the Appeal Brief. The examiner discusses this portion of the Appeal Brief on pages 34-35 of the Examiner's Answer, stating that the cited dictionary reference was not provided and could not be evaluated by the examiner. The examiner then goes on to cite two other documents in support of his position. Appellants did not file a Reply Brief.

An appeal should be contested upon a fixed record, not upon an ever expanding and shifting record as here. It does not appear that appellants made the requisite showing under 37 CFR § 1.195 in presenting new evidence in conjunction with this appeal nor is it is apparent that the examiner had authority to rely upon new evidence in support of his position. Under these circumstances, we decline to consider the issue.

nucleotide molecule of SEQ ID No. 1. Why does knowledge that a similar molecule may exist in another organism represent a substantial utility?

The same analysis holds for the stated utility that a nucleic acid molecule may be used in a "chromosome walk." Id., pages 16-17. In presenting this argument, appellants run afoul of the confusion engendered as to the source of the present nucleic acid molecules. Appellants' argument at page 17 of the Appeal Brief is couched in terms of the ability to isolate a promoter that is active in young seed pods (5 to 15 days after flowering). It appears that this argument is premised upon the fact that the nucleic acid molecule of the present invention was obtained from young seed pods. However, as explained above, the examples of the specification state that the nucleic acid molecule was obtained from young seeds collected from young pods.

Appellants state that the examiner denigrated the "chromosome walk" utility by stating in the Final Rejection that "[a]ny nucleic acid molecule from any plant cell generally serves this purpose...." Appeal Brief, page 16. Appellants argue in essence that despite the fact that the argued utility applies to all ESTs, there is no legal requirement that an invention's utility be "unique" to the invention, i.e., an invention can be a member of a class, where all the members of the class share a common utility.

First, appellants have only been required to identify a utility that is specific to the invention claimed. See, e.g., Brenner, 383 U.S. at 534, 148 USPQ at 695 (An invention does not have utility sufficient to satisfy § 101 until it is "refined and developed" to the point of providing a specific benefit in currently available form.). An invention certainly can have a utility that is shared by other compounds or compositions. Take, for

example, an application that claims ibuprofen and discloses that it is useful as an analgesic. No one would argue that a claim to ibuprofen lacks utility simply because aspirin and acetaminophen are also useful as analgesics. On the other hand, not every utility will satisfy § 101, even if the utility is shared by a class of inventions. Assume that the above-described application did not disclose that ibuprofen was an analgesic but only disclosed that it is useful because it can be used to fill a jar, which would then be useful as a paperweight. There would be little doubt that this disclosed utility would not satisfy § 101, even though the utility is shared by a large class of inventions, viz., those whose physical embodiments have mass. So while a utility need not be unique to a claimed invention, it must nonetheless be specific, and in currently available form, in order to satisfy § 101.

Nor does Dr. Wiegand's declaration assist appellants in this portion of their position on appeal. Dr. Wiegand discusses the use of EST's to generate probes in paragraphs 14-17 of his declaration. However, that work is based upon a synthetic probe stated to be "a true enough copy of SEQ ID No. 1." It is not apparent why evidence based upon "a true enough copy" of SEQ ID No. 1 is relevant in this appeal.

c. Other Arguments[8]

Appellants argue that the specification describes other utilities for the claimed nucleic acid molecules including "introduction of the claimed nucleic acid molecules into a plant or plant cell (either as sense or antisense inhibitors), which can then be used to screen for compounds such as a herbicide." Appeal Brief, page 10. Specifically, appellants argue that a compound can be provided to both an antisense plant and a control plant not having antisense, with the effect of the compound on the plant being monitored. Appellants analogize this proposed procedure to a "cell-based assay" which appellants assert to have a "legally sufficient utility." Id.

Suffice it to say that an otherwise uncharacterized nucleic acid molecule is being claimed in this application, not an assay. The portion of the specification cited in support of this argument (page 64) indicates that the nucleic acid molecule must be introduced into a plant cell and transcribed using an appropriate promoter to result in the co-suppression of an endogenous protein. The specification does not indicate that such a method is feasible when the nucleic acid to be used is uncharacterized as here. Such a use does not provide a specific or substantial benefit in currently available form.

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[8] Appellants present arguments in the Appeal Brief responding to issues apparently raised by the examiner previously but not maintained in the statement of rejection in the Examiner's Answer. For example, appellants argue that the examiner was incorrect as characterizing the claimed nucleic acid molecules as "tools" in the Final Office Action and Advisory Action. Appeal Brief, pages 11-12. However, the examiner does not characterize the claimed nucleic acid molecules in that manner in stating the utility rejection on pages 4-7 of the Examiner's Answer. Appellants also present arguments on pages 23-26 of the Appeal Brief in regard to whether the claimed nucleic acid molecules correspond to a pseudogene or are an artifact. However, in presenting his position on appeal the examiner does not rely upon either theory in stating the rejection, Examiners Answer, pages 4-7. Apparently, the examiner no longer relies upon these rationales. Thus, we need not consider these issues.

Appellants also argue that the claimed nucleic acids are useful to measure the level of mRNA in a sample through use of microarray technology and use as molecular markers. Appeal Brief, pages 10-11. In regard to microarrays, appellants argue that it is "standard practice" to screen populations of nucleic acids with EST sequences without characterizing each and every target mRNA. Reference to para. 14 of the Wiegand declaration is made in support. Appeal Brief, page 11, n. 5. Dr Wiegand states "Soybean DNA clones are routinely used to detect expression levels of corresponding naturally occurring soybean nucleic acids. A nucleic acid molecule of SEQ ID NO: 1 can also certainly be used to detect expression level. Use of a nucleic acid molecule representing an EST as an expression probe is a practical use because it enables the detection of changes in expression of a particular gene." Wiegand decl., para. 14.

We find that the asserted utility of the claimed nucleic acid—as one component of an assay for monitoring gene expression—does not satisfy the utility requirement of § 101. Such a use does not provide a specific benefit in currently available form.

We accept, for argument's sake, that a person skilled in the art could use the claimed nucleic acid, in combination with other nucleic acids, to monitor changes in expression of the gene that encompasses the nucleic acid depicted in SEQ ID NO: 1. However, the specification provides no guidance which would allow a skilled artisan to use data relating to expression of such a gene in any practical way. The specification simply provides no guidance regarding what the SEQ ID NO: 1-specific information derived from a gene expression experiment would mean.

Suppose, for example, that a researcher found that SEQ ID NO: 1 expression was increased when a cell was treated with a particular agent. The specification provides no basis on which a skilled worker would be able to determine whether that result is meaningful. Maybe the meaning in a change in SEQ ID NO: 1 expression would depend on other factors, but again the specification provides no hint what other factors might be important. Would it depend on what agent is used, what cell type is used, the behavior of other genes (if so, which genes and what behavior is significant), the degree of increase? The specification simply provides no guidance as to how to interpret the results that might be seen using SEQ ID NO: 1 in a gene expression assay.

In effect, appellants' position is that the claimed nucleic acids are useful because those of skill in the art could experiment with them and figure out for themselves what any observed experimental results might mean. We do not agree that such a disclosure provides a "specific benefit in currently available form." Rather, the present case seems analogous to Brenner. In Brenner, the applicant claimed a method of making a compound but disclosed no utility for the compound. 383 U.S. at 529, 148 USPQ at 693. The Court held that a process lacks utility if it produces a product that lacks utility. Id. at 534, 148 USPQ at 695. Here, appellants claim a product asserted to be useful in a method of generating gene-expression data, but the specification does not disclose how to interpret those data. Just as the process claimed in Brenner lacked utility because the specification did not disclose how to use the end-product, the products claimed here lack utility, because even if used in gene expression assays, the

specification does not disclose how to use SEQ ID NO: 1-specific gene expression data.

Here, appellants assert that SEQ ID NO: 1, along with every other expressed soybean gene or protein, or for that matter, any expressed gene or protein, can be used to monitor changes in gene expression. However, without additional information, any observed results of changed expression of SEQ ID NO: 1 would have no meaning. The specification in effect discloses that the claimed nucleic acids can be used to monitor gene expression, and those of skill in the art will figure out what to do with the gene expression data. This utility is not substantial; it does not provide a specific benefit in currently available form.

Assuming arguendo that a generic gene expression assay—one based on monitoring expression of thousands of uncharacterized nucleic acids would provide a useful tool for, e.g., drug discovery, it does not follow that each one of the nucleic acids represented in the assay individually has patentable utility. Although each nucleic acid in the assay contributes to the data generated by the assay overall, the contribution of a single nucleic acid—its data point—is only a tiny contribution to the overall picture. The Brenner Court held that § 101 sets more than a de minimis standard for utility. Therefore, the patentable utility of a gene expression assay, for example, does not necessarily mean that each tiny component of the assay also has patentable utility. A patentable utility divided by a thousand does not necessarily equal a thousand patentable utilities. Each claimed invention must be shown to meet § 101's utility requirement in order to be patentable; it must provide a specific benefit in currently

available form. Providing a single data point among thousands or millions, even if the thousands or millions of data points collectively are useful, does not meet this standard. The Supreme Court noted that the patent system contemplates a basic quid pro quo: in exchange for the legal right to exclude others from his invention for a period of time, an inventor discloses his invention to the public. See Brenner, 383 U.S. at 534, 148 USPQ at 695. The Brenner Court held that the grant of patent rights to an applicant is justified only by disclosure of an invention with substantial utility – a specific benefit in currently available form. Until the invention has been refined and developed to this point, the Court held, the applicant has not met his side of the bargain, and has not provided a disclosure sufficient to justify a grant of the right to exclude others. See id.

We reach the same conclusion in regard to appellants assertion that the nucleic acid depicted in SEQ ID NO: 1 is useful as a molecular marker or probe. It is not seen that the one data point which may be provided by using the uncharacterized nucleic acid molecule of SEQ ID NO: 1 as a molecular marker or probe represents a substantial use.

Appellants argue that ESTs have real world value as seen from the "growth of a multi-million dollar industry in the United States premised on the usefulness of ESTs." Appeal Brief, pages 19-21. Reliance is placed on paragraph 6 of the Wiegand declaration in support of this argument. Dr. Wiegand statements in this paragraph of his declaration refer to EST databases, clone sets and microarrays. Suffice it to say, the claims on appeal are not directed to EST databases, clone sets and/or microarrays. Again, it is not seen that the one data point which may be provided by using the

uncharacterized nucleic acid of SEQ ID NO: 1 in such devices represents a substantial use.

2. Enablement

There are two rationales set forth in the Examiner's Answer for this rejection. First, claims 1-3 are considered to be non-enabled "since the claimed invention is not supported by either a specific asserted utility or a well established utility for the set forth [in support of the § 101 rejection]. one skilled in the art clearly would not know how to use the claimed invention." Examiner's Answer, page 7. The examiner's second position focuses on claims 1 and 3 and their use of the transitional phrases "comprising" and "consisting essentially."

In regard to the first rationale, it appears that the rejection is simply a corollary of the finding of lack of utility. Thus, our conclusion with respect to the § 101 issue will also apply to this aspect of the § 112 (enablement) issue.[9] On this basis we affirm the enablement rejection.

3. Written description

Only claims 1 and 3 are rejected under this section of the statute. The examiner has concluded that the use of the transitional phrases "comprising" and "consisting essentially of" in these claims results in appellants claiming an "astronomically large

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[9] Under these circumstances we need not reach the examiner's second rationale. However, we point out that the second rationale is premised upon an erroneous claim construction, i.e., the transitional phrases "comprising" and "consisting essentially of" are equivalent. If prosecution is resumed on this subject matter, the examiner should revisit the issue and construe "comprising'" and "consisting essentially of" consistent with their well defined meanings. Also, as noted previously, the examiner did not make of record a fact-based analysis of the Wands factors. We urge the examiner in making any future enablement rejection, the rejection include an explicit analysis of the Wands factors.

genus of nucleic acid molecules" which are not "adequately describe[d]" by SEQ ID NO: 1. Examiner's Answer, page 10.

We do not find that this issue is ripe for review at this time and therefore decline to reach the merits of this rejection. The Appeal Brief was filed on January 31, 2001 and the Examiner's Answer was entered on August 6, 2001. Prior to the briefing in this appeal, the USPTO issued "Guidelines for Examination of Patent Applications under 35 U.S.C. § 112, ¶ 1 "Written Description" Requirement, 66 Fed. Reg. 1099 (Jan. 5, 2001) (Guidelines). Neither appellants nor the examiner discussed the Guidelines and determined what affect, if any, they may have on their respective positions. In addition, the Federal Circuit has recently considered written description issues involving claims directed to nucleotide sequences and their use in hybridization assays in Enzo Biochem, Inc. v. Gen-Probe, Inc., 296 F.3d 1316, 63 USPQ2d 1609 (Fed. Cir. 2002).

We believe a reasoned review of this rejection can only be performed after appellants and the examiner have had an opportunity to review the Guidelines and the court's opinion in Enzo. Since our affirmance of the utility rejection and the enablement rejection to the extent it is a corollary of the utility rejection constitutes a disposition of the appeal, we see no reason to remand the case for consideration of this issue now. Rather, if prosecution is resumed in this case, appellants and the examiner should revisit the issue and take into account the Guidelines and the guidance provided in Enzo.

Time Period For Response

This opinion contains a new ground of rejection pursuant to 37 CFR § 1.196(b). 37 CFR § 1.196(b) provides that, "A new ground of rejection shall not be considered final for purposes of judicial review."

37 CFR § 1.196(b) also provides that appellant, WITHIN TWO MONTHS FROM THE DATE OF THE DECISION, must exercise one of the following two options with respect to the new ground of rejection to avoid termination of proceedings (§ 1.197(c)) as to the rejected claims:

> (1) Submit an appropriate amendment of the claims so rejected or a showing of facts relating to the claims so rejected, or both, and have the matter reconsidered by the examiner, in which event the application will be remanded to the examiner. . . .
>
> (2) Request that the application be reheard under § 1.197(b) by the Board of Patent Appeals and Interferences upon the same record. . . .

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED; 196(b)

Bruce H. Stoner, Jr., Chief
Administrative Patent Judge

William F. Smith
Administrative Patent Judge

Toni R. Scheiner
Administrative Patent Judge

) BOARD OF PATENT
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) INTERFERENCES

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APPENDIX

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